PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#34
M.G.J
10/26/01

In re Patent Application

Brockhaus et al.

Group: 1646

Serial No. 08/444,790, filed May 19, 1995

Examiner: J. Murphy

For: **HUMAN TNF RECEPTOR**

COMMUNICATION AND INFORMATION DISCLOSURE STATEMENT

Nutley, New Jersey 07110
October 17, 2001

Commissioner of Patents
Washington, D.C. 20231

Dear Sir:

This Communication is filed in response to the July 17, 2001 Office Action issued in connection with the above-identified patent application.[1] A response to this Office Action is due October 17, 2001.

Reconsideration is requested in view of the following remarks. Claims 62-77 are pending in the subject application and were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Wallach (U.S. Patent No. 5,981,701).[2] Specifically, it was

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[1] The original Office Action was mailed April 17, 2001 but was not received by applicants. Applicants' undersigned attorney contacted the Examiner and an Office Action restarting the time period for response was mailed on July 17, 2001.

[2] Applicants point out that rejections based on analogous Wallach documents have been overcome in related applications.

alleged that Wallach discloses a TNF inhibitory protein with a molecular weight of 40-80 kD that comprises an amino acid sequence that is identical to the sequence of the protein claimed in the instant application. Wallach was also alleged to set forth methods to produce TNF inhibitor protein recombinantly.

Contrary to the position set forth in the Office Action, Wallach does not disclose applicants' claimed invention.

Applicants' claimed invention relates to homogenous protein that binds human tumor necrosis factor. Independent claim 62 requires that the protein have an apparent molecular weight of about 55 kilodaltons on a non-reducing SDS-polyacrylamide gel and comprises the amino acid sequence of Figure 1. Independent claim 63 requires that the protein comprises the amino acid sequence of Figure 1 beginning at amino acid number 1 and ending approximately at amino acid number 180. Independent claim 66 requires that the protein has an apparent molecular weight of about 55 kilodaltons on a non-reducing SDS-polyacrylamide gel and is encoded by the DNA sequence of Figure 1. Independent claim 69 requires that the protein comprises the amino acid sequence encoded by the DNA sequence of Figure 1 beginning at nucleotide number 121 and ending at approximately nucleotide number 627.

In contrast, Wallach discloses a different TNF inhibitory protein that can be isolated from human urine. While a general disclosure of recombinant techniques is disclosed by Wallach together with the suggestion to try such techniques on the Wallach TNF inhibitory protein, there is no disclosure of any recombinantly produced TNF inhibitory protein.

Amino Acid Sequence

The amino acid sequence of Wallach is different from the amino acid sequence of applicants' claimed proteins. The protein of Wallach is characterized by containing at its N-terminus the following amino-acid sequence: Asp-Ser-Val-Cys-Pro-Gln-Gly-Lys-Tyr-Ile-His-Pro-Gln-X-Asn-Ser (Wallach, column 4, lines 26-39, column 10, lines 21-28, and column 12, lines 12-23). In marked contrast, applicants' claimed amino acid sequence of Figure 1 beginning at amino acid number 1 is: Leu-Val-Pro-His-Leu-Gly-Asp-Arg-Glu-Lys-Arg-Asp-Ser-Val-Cys-Pro. Since the protein of Wallach and applicants' claimed receptor protein have different N-terminus amino acid sequences, they are clearly different proteins, and thus patentably distinct from each other.

Applicants' claims 62-68 recite the above-mentioned N-terminus amino acids. Accordingly, these claims are neither taught nor suggested by Wallach.

Applicants' amino acid sequence encoded by the DNA sequence of Figure 1 beginning at nucleotide number 121 and ending at approximately nucleotide number 627 is not disclosed by Wallach. Claims 69 and dependent claims 70-77 are directed to a homogeneous protein that comprises the amino acid sequence encoded by the DNA sequence of Figure 1 beginning at nucleotide number 121 and ending at approximately nucleotide number 627. As stated above, Wallach does not teach or suggest applicants' claimed homogeneous receptor protein (claims 62 and 66). Although Wallach discloses the possibility that its protein may contain "active fractions" (Wallach at column 4-5 bridging paragraph), Wallach provides no guidance for selecting any particular fraction. Since Wallach fails to provide any guidance with respect to identifying particular active fragments of its own protein, Wallach clearly cannot provided guidance for identifying active fragments in a different protein. Accordingly, no teaching or suggestion in Wallach

could render obvious applicants' amino acid sequence encoded by the DNA sequence of Figure 1 beginning at nucleotide number 121 and ending at approximately nucleotide number 627.

Applicants' claims 70-77 contain the above-mentioned amino acid sequence that is nowhere to be found in Wallach. Accordingly, these claims are neither taught nor suggested by Wallach.

Molecular Weight

Contrary to the position set forth in the Office Action, Wallach does not disclose a protein that "has a molecular weight of 40-80 kD." Wallach discloses that when "crude preparations thereof derived from human urine concentrate were chromatographed under Ultrogel ACA 44 gel filtration column, it [sic.] showed an apparent molecular weight of 40-80 Kda" (Wallach, column 4, lines 12-16). This molecular weight was for a **crude preparation**, not a homogenous protein as in applicants' claimed invention. Wallach states that the "substantially purified protein, which is substantially free of proteinacous impurities, has a molecular weight of about 26-28 Kda when analysed by SDS.PAGE under reducing conditions" (Wallach, column 4, lines 16-21). In distinction, applicants' claims 62 and 66-68 recite an apparent molecular weight of about 55 kilodaltons on a non-reducing SDS-polyacrylamide gel. The Wallach protein has a molecular weight that differs from that claimed by applicants.

In summary, applicants' claims are directed to proteins that are neither taught nor suggested by Wallach. Applicants' claimed proteins differ in both amino acid composition (in particular at the N-terminus) and molecular weight.

In view of the above, applicants request withdrawal of all rejections under 35 U.S.C. §102.

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, applicants respectfully direct the Examiner's attention to the document listed on enclosed Form PTO-1449. Document C33 listed on Form PTO-1449 is enclosed.

Also enclosed is a Office Action, dated April 12, 2001, which was issued by the European Patent Office in the connection with application 99 100 703.0-2118 which corresponds to the captioned application. Documents other than C33 had previously been provided to the Patent Office.

Consideration of the document cited on Form PTO-1449 is requested.

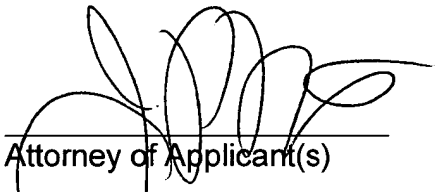
Since the Information Disclosure Statement is submitted more than three (3) months after being brought to applicants' attention, there is enclosed a Fee Sheet.

Applicants request reconsideration, withdrawal of all rejections, and the issuance of a Notice of Allowance.

If a telephone conference would be of assistance in furthering prosecution of the subject application, applicants request that the undersigned attorney be contacted at the number below.

No fee, other than the fee for filing the Information Disclosure Statement, is required in connection with the filing of this Communication. If any additional fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,



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